

4412. Misbranding of phenylbutazone tablets, chloramphenicol capsules, and conjugated estrogens tablets. U. S. v. Donahoe Pharmacy, Inc., and Victor Goldman. Pleas of guilty. Fine of \$150 against corporation and \$50 against individual. (F. D. C. No. 35763. Sample Nos. 45150-I, 45531-L, 45532-L, 45557-L to 45559-L, incl.)

INFORMATION FILED: February 2, 1954, District of Massachusetts, against Donahoe Pharmacy, Inc., Natick, Mass., and Victor Goldman, president of the corporation.

NATURE OF CHARGE: On or about June 24 and July 1, 6, and 13, 1953, while a number of *phenylbutazone tablets*, *chloramphenicol capsules*, and *conjugated estrogens tablets* were being held for sale at Donahoe Pharmacy, Inc., after shipment in interstate commerce, the defendants caused a number of the *phenylbutazone tablets* and *chloramphenicol capsules* to be dispensed upon requests for refills of written prescriptions without obtaining authorization by the prescribers and caused a number of *conjugated estrogens tablets* to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 26, 1954. The defendants having entered pleas of guilty, the court fined the corporation \$150 and the individual \$50.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4413. Misbranding of Special Formula tablets. U. S. v. 1 Drum, etc. (F. D. C. No. 36491. Sample No. 51025-L.)

LIBEL FILED: April 20, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about December 24, 1953, by Faraday Laboratories, from Newark, N. J.

PRODUCT: *Special Formula tablets*. 1 drum containing 25,000 red-coated tablets and 1 drum containing 25,000 green-coated tablets at Long Island City, N. Y., in possession of Edward J. Moore Sons, together with a number of loose labels intended for use in repackaging the tablets.

LABEL, IN PART: (Drum) "Spec. Formula S. C. Red (or Green) Each tablet contains: Quinine HCL. 2½ gr. Dried Ferrous Sulfate 1 gr. Ext. Black Haw Bk. Tree 1 gr. Ext. Wild Yam Root 1 gr. Jamaica Ginger ½ gr. Aloin ¼ gr. Caution: Federal law prohibits dispensing without prescription. * * * Bulk Shipment For Repackaging and Relabeling Only."; (loose labels) "Red Sanger Number 5 (or Green Corbin No. 10) Contains: Dried Ferrous Sulfate (Iron 20 mgs.), Quinine Hydrochloride, Aloin, P. E. Wild Yam, P. E. Black Haw, and Ginger. For the relief of pains not due to organic disease ordinarily associated with the menstrual period. Dose: Adults only, 2 capsules before each meal (6 capsules per day) during menstruation. * * * Contains 24 Capsules Distributed by Sanger & Company (or Corbin Capsule Company) 10-93 Jackson Ave., Long Island City 1, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use since their labeling did not bear a statement of the recommended or usual dose, nor information as to the use of the drug by practitioners licensed by law to administer such drug; and such information was not contained in scientific literature. The tablets were misbranded in such respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the tablets, namely, the label designated "Red Sanger Number 5" intended for use in repackaging the red-coated tablets and the label designated "Green Corbin No. 10" intended for use in repackaging the green-coated tablets, contained statements which represented and suggested that the tablets (red-coated and green-coated tablets) were efficacious in the relief of pain not due to organic disease ordinarily associated with the menstrual period. Such statements were false and misleading since the tablets were not efficacious in the relief of pain not due to organic disease ordinarily associated with the menstrual period. The tablets were misbranded in such respect while held for sale after shipment in interstate commerce.

DISPOSITION: May 20, 1954. Default decree of condemnation and destruction.

4414. Misbranding of Devine's Zina-Ray oil and Devine's inhaler. U. S. v. 432 Bottles, etc. (F. D. C. No. 36472. Sample Nos. 61106-L, 61107-L.)

LABEL FILED: On or about April 1, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 23, 1953, and February 5, 1954, from Chicago, Ill.

PRODUCT: 720 1-ounce bottles and 4 cartons, each carton containing 12 dozen 3-ounce bottles, of *Devine's Zina-Ray oil*, and 40 boxes, each containing 200 *Devine's inhalers*, at Kansas City, Mo., in possession of Susan Buckhinder.

RESULTS OF INVESTIGATION: The articles were promoted for sale through demonstrations given by Mrs. Buckhinder, a representative of Devine's Remedies, Inc., Chicago, Ill. During the course of these demonstrations, Mrs. Buckhinder would recommend the articles for use in the treatment and prevention of various diseases and conditions.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of sinus, migraine headaches, arthritis, neuritis, lumbago, and asthma, and for preventing tonsillitis, laryngitis, bronchitis, and pneumonia, which were the conditions and purposes for which the articles were intended. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 24, 1954. Default decree of forfeiture and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4415. Adulteration and misbranding of liver injection. U. S. v. Bio-Ramo Drug Co., Inc., and Dr. Clifford W. Price. Pleas of not guilty. Tried to the court. Verdict of guilty against corporation; motion granted for dismissal of charge against individual. Fine of \$750, plus costs, against corporation. (F. D. C. No. 35557. Sample No. 26462-L.)

INFORMATION FILED: January 6, 1954, District of Maryland, against Bio-Ramo Drug Co., Inc., Baltimore, Md., and Dr. Clifford W. Price, technical director of the corporation.

ALLEGED SHIPMENT: On or about February 26, 1953, from the State of Maryland into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Liver Injection Crude," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since each cubic centimeter of the